Remarks

Claims 1-12 and 14-56 are pending upon entry of the foregoing amendments.

Amendments to the Claims

Claims 1, 3, 31, 32, 33, 46, and 50 have been amended to specify that the matrix material is hydrophobic. Support for these amendments can be found in the specification, for example, at page 30, lines 24-25. Claim 11 has been amended to comport with the amendment to claim 1. Claim 13 has been cancelled.

Rejection under 35 U.S.C. § 103

Claims 1-7, 10-12, 14-21, 27, 30, 32-36, 38-48, and 50-53 are rejected under 35 U.S.C. § 103(a) as obvious over U.S. Patent No. 6,395,300 to Straub et al. (hereinafter "Straub"). The rejection is respectfully traversed if applied to the claims as amended.

Applicants' Claimed Methods and Compositions

Most pharmaceutical agents delivered by inhalation are *immediate* release formulations that must be inhaled multiple times per day, which discourages patient compliance (Pg. 1, Lns. 17-19). The frequent inhalation dosing of immediate release formulations leads to pharmaceutical agent levels that peak and trough, causing undesirable toxicity or inadequate efficacy (Pg. 1, Lns. 19-21). In contrast with these typical formulations, Applicants' claimed methods and formulations use microparticles comprising a *hydrophobic* matrix material to provide *sustained* drug release. Specifically, Applicants have discovered that the composition of the microparticles (e.g., the matrix material and pharmaceutical agent) may be selected in combination with geometric size and average porosity to provide *delayed* release and *avoid* the burst effect associated with immediate release formulations (Pg. 7, Lns. 7-9).

Straub

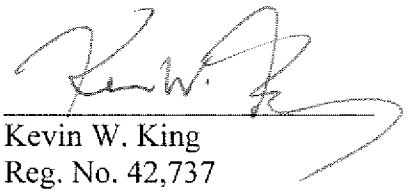
In contrast with Applicants' claimed methods and formulations, which use *hydrophobic* matrix material to *delay* drug release, Straub discloses that drugs, especially low aqueous solubility drugs, can be provided in microparticles so as to *enhance* the dissolution of the drug (Abstract). In order to speed up drug release, Straub specifies the use of drug matrices that include *hydrophilic* excipients and *hydrophilic* polymers (Col.8, Lns. 11 and 36). These *hydrophilic* materials allow water to penetrate the matrices and *increase* the dissolution of the drug (Col. 8, Lns. 14-21). Because Straub teaches the use of the *hydrophilic* matrices materials in order to *increase* drug release, it teaches away from the use of *hydrophobic* matrices materials for *sustained* drug release. In other words, Straub is directed to *increasing* the rate of release of a hydrophobic drug that otherwise might not release in a therapeutically effective amount, while in the instant application, the Applicants' claims are directed to microparticles for *sustaining* release of a drug over a longer period in a therapeutically effective amount, keeping it from releasing too quickly. Applicants' claimed methods and formulations are therefore clearly non-obvious over Straub.

Conclusions

For the foregoing reasons, Applicants submit that the claims are patentable over the prior art of record. Allowance of claims 1-12 and 14-56 is therefore respectfully solicited.

The undersigned respectfully invites the Examiner to contact him by telephone (404.853.8068) if any outstanding issues can be resolved by conference or examiner's amendment.

Respectfully submitted,



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